

deficit/hyperactivity disorder, an autoimmune disease, or Crohn's disease. Claims 12-30 and 56-66 are directed to a method of treating irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, or Crohn's disease. Claims 31-55 are directed to a kit for the diagnosis or treatment of irritable bowel syndrome, fibromyalgia, chronic fatigue syndrome, depression, attention deficit/hyperactivity disorder, an autoimmune disease, or Crohn's disease.

Applicant's Amendments

The amendment at page 35, lines 18-25, in Table 3, is to correct an obvious typographical error.

Applicant has canceled Claims 1-11 and 31-55, without prejudice, as being directed to a non-elected group.

The Restriction Requirement and Applicant's Election

The Examiner required restriction, under 35 U.S.C. § 121, and required Applicant to elect a single invention to which the claims must be restricted.

The Examiner presented the following two groups:

1. Group I; Claims 1-11, drawn to a method of diagnosing a disease corroborated by the presence of SIBO.
2. Group II; Claims 12-30 and 56-66, drawn to a method of treating a disease involving SIBO by at least partially eradicating the SIBO.
3. Group III; Claims 31-55, drawn to a kit for detecting and treating diseases related to SIBO comprising a substrate and a breath sampling container.

In response Applicant elects **Group II** without traverse. Applicant's election is made with a complete reservation of all rights under 35 U.S.C. § 121.

Examiner's Requirement of an Election of Species and Applicant's Response

1. The Examiner required elections of species, under 35 U.S.C. § 121. The Examiner stated that currently, Claims 1, 12, and 31 are generic. The Examiner presented for election the following species of diseases addressed by the Claim Groups I, II, or III of the invention:

- (A) irritable bowel syndrome (IBS) and Crohn's disease;
- (B) fibromyalgia;
- (C) chronic fatigue syndrome;
- (D) depression
- (E) attention deficit/hyperactivity disorder (ADHD); or
- (F) an autoimmune disease.

Applicant elects: **(A)** irritable bowel syndrome (IBS) and Crohn's disease (e.g., Claims 12-30 and 56-66).

Applicant's election is made with a complete reservation of all rights under 35 U.S.C. § 121. The Examiner noted that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species. Applicant asserts, in concurrence with the Examiner, that in elected Group II, allowable generic claims exist in the application, for example, Claim 12.

2. Within Claim Group II, the Examiner required Applicant to make an election of one of the following species, wherein the at least partial eradication of SIBO is accomplished using:

- (A) an antimicrobial agent;
- (B) a probiotic agent;
- (C) intestinal lavage or enema;
- (D) a modified diet; or
- (E) a prokinetic agent.

The Examiner stated that Applicant was required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The Examiner stated that currently, Claim 12 is generic.

In response, Applicant elects: (E) a prokinetic agent (e.g., Claims 12, 21-26, and 56-66).

Applicant's election is made with a complete reservation of all rights under 35 U.S.C. § 121. The Examiner noted that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species. Applicant asserts, in concurrence with the Examiner, that in elected Group II, allowable generic claims exist in the application, for example, Claim 12.

3. Within Claim Group II, the Examiner required Applicant to make a further election of one of the following species, wherein the method of treating further comprises:

- (A) no additional active ingredients;
- (B) a pro-inflammatory cytokine antagonist;
- (C) an anti-inflammatory cytokine or an agent against thereof; or
- (D) an agent that modifies afferent neural feedback or sensory

perception.

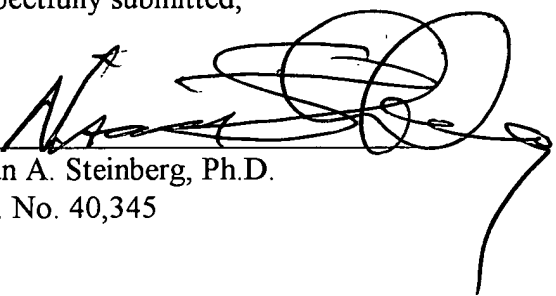
The Examiner stated that Applicant was required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall

be restricted if no generic claim is finally held to be allowable. The Examiner also stated that currently, Claim 12 is generic.

In response, Applicant elects: **(D)** an agent that modifies afferent neural feedback or sensory perception (e.g., Claims 12, 21-26, and 56-66).

Applicant's election is made with a complete reservation of all rights under 35 U.S.C. § 121. The Examiner noted that upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species. Applicant asserts, in concurrence with the Examiner, that in elected Group II, allowable generic claims exist in the application, for example, Claim 12.

Respectfully submitted,

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MARKED VERSION WITH CHANGES MADE

In the specification:

At page 35, lines 18-25, please delete Table 3 and insert therefor:

--Table 3. VAS scores by SLE patients reporting before and after anti-biotic treatment.

Symptom	Before Antibiotic	After Antibiotic	P-value
Bloating	<u>3.0 ± 2.0</u>	<u>1.3 ± 1.3</u>	<u>0.1</u>
[3.0 ± 2.0	1.3 ± 1.3	0.1]	
Joint Pains	2.5 ± 1.5	0.5 ± 0.6	0.04
Gas	3.3 ± 1.7	1.9 ± 1.7	0.3
Fatigue	4.6 ± 1.0	3.5 ± 1.4	0.3

In the claims:

Please cancel Claims 1-11 and 31-55, without prejudice, as being directed to a non-elected group. No claims are amended.